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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,753	11/30/2001	Lawrence J. Mulligan	P-9115.00	3713

27581 7590 07/27/2004
MEDTRONIC, INC.
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EXAMINER

MACHUGA, JOSEPH S

ART UNIT PAPER NUMBER

3762

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/997,753	MULLIGAN ET AL.	
	Examiner	Art Unit	
	Joseph S. Machuga	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 and 19-30 is/are rejected.
- 7) Claim(s) 18 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

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Response to Arguments

Applicant's arguments have been given careful consideration. Regarding the drawings the two external electrodes are not shown in the drawings as required by 37 CFR 1.83(a) and so the requirement still remains.

Regarding the Cohen #4984572 reference. All the particulars of the claims are provided for. Specifically the first sensor 20, a first circuit 18 and a processing circuit 12 that receives those two inputs. The system determines therefrom the mean pulmonary arterial pressure (note column 4, lines 23+) through an internal algorithm. While other variations are envisioned as noted by applicant this citation clearly states placing the sensor in the right ventricle or the left ventricle to calculate the MPAP, MPVP and MPCWP.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the two external electrodes recited in claim 3 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4 and 6 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cohen #4984572. Regarding claim 4 the electrode is considered near the implantable device since it is located in the left ventricle.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen #4984572.

5. Cohen teaches adding pressure sensors to both the right ventricle and left ventricle to provide accurate pressure measurements. Given this disclosure it would have been obvious to one of ordinary skill in the art to add pressure sensors to both ventricles to provide an accurate measurement of the MPAP as well as to provide sensors to determine the pulmonary systolic arterial pressure and the pulmonary

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diastolic arterial pressure, features commonly known to be ascertainable from these locations.

6. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen #4984572 in view of Halperin et al #5810735.

7. Cohen discloses an implantable pacemaker having a pressure sensor, sensing electrodes to monitor the EKG signal and pacing electrodes. The circuitry computes from the data the mean pulmonary arterial pressure and provides appropriate therapies in response. Not disclosed by this reference is the external device.

8. Halperin et al disclose an implant that includes an external device that receives data from the implant to perform calculations (such as the create a histogram), reprogram the implant or adjust the delivery of drugs or other therapies.

9. Given Halperin et al's disclosure it would have been obvious to one of ordinary skill in the art to modify Cohen's implant to include a transmitter and external receiver to perform the desired calculations, or to reprogram the implant or to adjust the delivery of drugs or other therapies.

10. Claims 13-17 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen #4984572 in view of Carney #5368040.

11. Cohen discloses an implantable pacemaker having pressure sensor, sensing electrodes to monitor the EKG signal and pacing electrodes. The circuitry computes from the data the mean pulmonary arterial pressure and provides appropriate therapies in response. Not disclosed by this reference is the use of the EGM signal and the pressure value to determine the MPAP.

12. Carney teaches using the EGM, pressure values from the R wave (which would also represent the maximum pressure change), systolic and diastolic times, etc. to determine the pulmonary arterial pressure (note column 2.)

13. Given Carney's teaching it would have been obvious to use the EGM and pressure values, R wave point, systolic and diastolic times, etc. to determine the MPAP in Cohen's device given this references teaching that it provides a good estimates of that pressure.

14. Claims 19-22 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Carney as applied to claims 13 and 23 above, and further in view of Halperin et al #5810735.

15. Halperin et al disclose an implant that includes an external device that receives data from the implant to perform calculations (such as the create a histogram), reprogram the implant or adjust the delivery of drugs or other therapies.

16. Given Halperin et al's disclosure it would have been obvious to one of ordinary skill in the art to modify the implant of the proposed combination to include a transmitter and external receiver to perform the desired calculations, or to reprogram the implant or to adjust the delivery of drugs or other therapies.

17. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

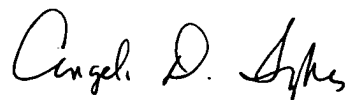
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on M-F 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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